



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gyula Hadlaczky et al. Art Unit : 1638
Serial No. : 09/724,726 Examiner : Georgia Helmer
Filed : November 28, 2000 Cust. No. : 20985
Conf. No. : 7776
Title : ARTIFICIAL CHROMOSOMES, USES THEREOF AND METHODS FOR
PREPARING ARTIFICIAL CHROMOSOMES

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

This Supplemental Information Disclosure Statement is filed with a Request for Continued Examination of the above-captioned application and prior to receipt of an Office Action. Thus, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (1 page) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

In accordance with the requirements of 37 C.F.R. §1.98, copies of an Australian Examination Report (Document I), issued March 23, 2006, in connection with corresponding Australian Patent Application No. 2004201732; two European Examination Reports (Documents II and III), issued September 9, 2005 and July 12, 2006, in connection with

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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie Serdian

corresponding European Patent Application No. 97920284.3; an Office Action (Document IV), issued September 22, 2006, in connection with U.S. Patent Application Serial No. 10/782,129; an Office Action (Document V), issued August 15, 2006, in connection with U.S. Patent Application Serial No. 10/287,313; and two Office Actions (Documents VI and VII), issued May 8, 2006, in connection with U.S. Patent Application Serial Nos. 10/219,694 and 10/808,689, are provided for consideration by the Examiner. The table below lists Documents I-VII and includes a column that provides a space next to each document to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document
	I	Copy of Australian Examination Report, issued March 23, 2006, in connection with corresponding Australian Patent Application No. 2004201732
	II	Copy of European Examination Report, issued September 9, 2005, in connection with corresponding European Patent Application No. 97920284.3
	III	Copy of European Examination Report, issued July 12, 2006, in connection with corresponding European Patent Application No. 97920284.3
	IV	Copy of Office Action, issued September 22, 2006, in connection with U.S. Patent Application Serial No. 10/782,129
	V	Copy of Office Action, issued August 15, 2006, in connection with U.S. Patent Application Serial No. 10/287,313
	VI	Copy of Office Action, issued May 8, 2006, in connection with U.S. Patent Application Serial No. 10/219,694
	VII	Copy of Office Action, issued May 8, 2006, in connection with U.S. Patent Application Serial No. 10/808,689

Provided herewith and submitted for consideration by the Examiner is a copy of an Australian Examination Report (Document I), issued March 23, 2006, in connection with corresponding Australian Patent Application No. 2004201732 (Attorney Docket No. 17084-004AU3/402CAU), which is a divisional of Australian Patent Application No. 38957/01, which is Divisional of Australian Patent Application No. 24512/97, which is a national stage filing of International Patent Application No. PCT/US97/05911, which claims priority to U.S. Patent Application Serial No. 08/629,822. The instant application is a divisional of U.S. Patent Application Serial No. No. 08/835,682 and ultimately claims priority to U.S. Patent Application Serial No. 08/629,822. Hence this application and Australian Patent Application No. 2004201732 claim priority ultimately to the same parent application. In the Australian

Examination Report, Examiner cites two documents: U.S. Patent No. 5,288,625 and European Patent Publication No. EP 0532050. These documents have already been made of record in the instant application in an Information Disclosure Statement, supplied with Forms PTO-1449 and copies of the cited documents, filed May 16, 2001.

Provided herewith and submitted for consideration by the Examiner are copies of two European Examination Reports (Documents II and III), issued September 9, 2005 and July 12, 2006, in connection with corresponding European Patent Application No. 97920284.3 (Attorney Docket No. 17084-004EP1/402EP), which is a national stage filing of International Patent Application No. PCT/US97/05911, which claims priority to U.S. Patent Application Serial No. 08/629,822. The instant application is a divisional of U.S. Patent Application Serial No. No. 08/835,682 and ultimately claims priority to U.S. Patent Application Serial No. 08/629,822. Hence this application and European Patent Application No. 97920284.3 claim priority ultimately to the same parent application. In the European Examination Report dated September 9, 2005, Examiner cites two references: D4 (WO9532297) and D17 (Waye and Willard, *Nucleic Acids Research* 15(18):7549-69 (1987)). In the European Examination Report dated July 12, 2006, Examiner cites three documents: D4 (WO9532297), D18 (Brown *et al.*, "Dissecting the centromere of the human Y chromosome with cloned telomeric DNA" *Human Molecular Genetics* 3(8):1227-1237 (1994)) and D19 (Nakahori *et al.*, "A human Y-chromosome specific repeated DNA family (DYZ1) consists of a tandem array of pentanucleotides", *Nuc. Acids Res.* 14(19):7569-7580 (1986)). D4 and D17 have already been made of record in the instant application in Information Disclosure Statements, supplied with Forms PTO-1449, filed May 16, 2001 and November 9, 2005. D18 and D19 are being made of record in this Information Disclosure Statement, supplied with Forms PTO-1449 and copies of the cited documents.

Provided herewith and submitted for consideration by the Examiner are copies of an Office Action (Document IV), issued September 22, 2006, in connection with U.S. Patent Application Serial No. 10/782,129 (Attorney Docket No. 17084-004016/402O), which is a continuation of U.S. Patent Application Serial No. 09/096,648, which is a continuation of U.S. Patent Application Serial No. 08/629,822. The instant application is a divisional of U.S. Patent Application Serial No. No. 08/835,682 and ultimately claims priority to U.S. Patent Application Serial No. 08/629,822. Hence this application and U.S. Patent Application Serial

No. 10/782,129 claim priority ultimately to the same parent application. In the Office Action, Examiner cites the following twenty-four documents:

- 1) Houdebine, "Production of pharmaceutical proteins from transgenic animals" *J. Biotech.* 34:269-287 (1994)
- 2) Kappell *et al.*, "Regulating gene expression in transgenic animals" *Curr. Opin. Biotech.* 3:548-553 (1992)
- 3) McGovern, "The barriers to interspecific hybridization in domestic and laboratory mammals. II. Hybrid sterility" *Br. Vet. J.* 132:68-75 (1976)
- 4) Montoliu *et al.*, "Germ Line Transmission of Yeast Artificial Chromosomes in Transgenic Mice" *Reprod. Fertil. Dev.* 6:577-584 (1994)
- 5) Mullins *et al.*, "Perspective Series: Molecular Medicine in Genetically Engineered Animals", *J. Clin. Invest.* 97(7):1557-1560 (1996)
- 6) Mullins *et al.*, "Transgenesis in nonmurine species" *Hypertension* 22(4):630-633 (1993)
- 7) Schedl *et al.*, "Transgenic mice generated by pronuclear injection of a yeast artificial chromosome", *Nucl. Acids Res.* 20(12):3073-3077 (1992)
- 8) Campbell *et al.*, "Totipotency or multipotentiality of cultured cells: applications and progress" *Theriogenology* 47:63-72 (1997)
- 9) Co *et al.*, "Generation of transgenic mice and germline transmission of a mammalian artificial chromosome introduced into embryos by pronuclear microinjection", *Chromosome Research* 8:183-191 (2000)
- 10) Hocheplied *et al.*, "Breaking the Species Barrier: Derivation of Germline-Competent Embryonic Stem Cells from Mus spretus x C57BL/6 Hybrids" *Stem Cells* 22:441-447 (2004)
- 11) Irvine *et al.*, "Engineering chromosomes for delivery of therapeutic genes", *Trends Biotechnol.* 23(12):575-583 (2005)
- 12) Kuhholzer *et al.*, "Advances in Livestock Nuclear Transfer", *Proc. Soc. Exp. Biol. Med.* 224:240-245 (2000)
- 13) Oback *et al.*, "Practical aspects of donor cell selection for nuclear cloning", *Cloning and Stem Cells* 4:169-174 (2002)
- 14) Sang, "Prospects for transgenesis in the chick" *Mechanisms of Development* 121:1179-1186 (2004)
- 15) Stice *et al.*, "Cloning: New breakthroughs leading to commercial opportunities", *Theriogenology* 49:129-138 (1998)
- 16) Wolf *et al.*, "Nuclear transfer in mammals: Recent developments and future perspectives", *J. Biotech.* 65:99-110 (1998)
- 17) Yanagimachi, "Cloning: Experience from the mouse and other animals", *Mol. Cell. Endocrin.* 187:241-248 (2002)
- 18) US 2003-0083293
- 19) US 2002-0160970
- 20) US 6743967

21) Saffery *et al.*, "Strategies for engineering human chromosomes with therapeutic potential", *J. Gene Med.* 4:5-13 (2002)

22) Brown *et al.*, "Mammalian artificial chromosomes" *Curr. Opin. Genet. Dev.* 6(3):281-288 (1996)

23) Brown *et al.*, "Artificial chromosomes: ideal vectors?", *TIBTECH* 18:218-223 (2000)

24) Moreadith *et al.*, "Gene targeting in embryonic stem cells: the new physiology and metabolism", *J. Mol. Med.* 75(3):208-16 (1997)

Documents 1-8 and 22 are being made of record in the instant application in this Supplemental Information Disclosure Statement, supplied with Forms PTO-1449 and copies of the cited non U.S. patent documents. Documents 9, 18-21 and 23-24 have already been made of record in the instant application in Information Disclosure Statements, supplied with Forms PTO-1449, filed May 14, 2001, March 29, 2006 and September 4, 2002. In accordance with the requirements of 37 C.F.R. §1.98, documents 10-17 are listed below in a table for consideration by the Examiner, and copies of the non U.S. patent documents are provided herewith.

Provided herewith and submitted for consideration by the Examiner are copies of an Office Action (Document V), issued August 15, 2006, in connection with U.S. Patent Application Serial No. 10/287,313 (Attorney Docket No. 17084-004015/402N), which is a divisional of the instant application. In the Office Action, Examiner cites the following documents:

25) Avramova, "Heterochromatin in Animals and Plants", *Plant Physiology* 129:40-49 (2000)

26) Bryant *et al.* "Origins and complexes: the initiation of DNA replication", *J. Experimental Biology* 52(355):193-202 (2001)

27) Ferl *et al.*, in Buchanan *et al.*, *Biochemistry & Molecular Biology of Plants*, American Society of Plant Physiologists, Rockville, MD 20855, p.324 (2000)

28) Hall *et al.*, "The rapidly evolving field of plant centromeres" *Curr. Opin. Plant Biol.* 7:108-114 (2004)

29) Willard, "Artificial Chromosomes Coming to Life", *Science* 290:1308-1309 (2000)

30) US 2006-0095984

31) US 5270201

32) US 6077697

33) US Application Serial No. 09/724,726 (the instant application)

Documents 25, 27 and 29 were cited by the Examiner in the instant application in an Office Action, dated January 17, 2003. Document 30 is being made of record in the instant application in this Supplemental Information Disclosure Statement, supplied with Forms PTO-1449 and copies of the cited non U.S. patent documents. Documents 31 and 32 have already been made of record in the instant application in Information Disclosure Statements, supplied with Forms PTO-1449, filed May 14, 2001 and July 25, 2003. Document 33 is the instant application. In accordance with the requirements of 37 C.F.R. §1.98, documents 26 and 28 are listed below for consideration by the Examiner, and copies of the non U.S. patent documents are provided herewith.

Provided herewith and submitted for consideration by the Examiner are copies of two Office Actions (Documents VI and VII), issued May 8, 2006, in connection with U.S. Patent Application Serial Nos. 10/219,694 (Attorney Docket No. 17084-004014/402M) and 10/808,689 (Attorney Docket No. 17084-004017/402P). U.S. Patent Application Serial Nos. 10/219,694 and 10/808,689 are divisionals of U.S. Patent Application Serial No. 09/724,693, which is a continuation of U.S. Patent Application Serial No. 08/835,682. The instant application is a divisional of U.S. Patent Application Serial No. No. 08/835,682. Hence this application and U.S. Patent Application Serial Nos. 10/219,694 and 10/808,689 claim priority ultimately to a common application. The following documents are cited by the Examiner in one or both of the Office Actions:

28) Hall *et al.*, "The rapidly evolving field of plant centromeres" Curr. Opin. Plant Biol. 7:108-114 (2004)

34) Assaad *et al.*, "Somatic and Germinal Recombination of a Direct Repeat in Arabidopsis", Genetics 132:553-566 (1992)

35) Borisjuk, N.V. *et al.*, "Tobacco ribosomal DNA spacer element stimulates amplification and expression of heterologous genes" Nature Biotech., 18:1303-1306 (2000)

36) Donald *et al.*, "Ribosomal RNA genes specific to the B chromosomes in *Brachycome dichromosomatica* are not transcribed in leaf tissue" Genome 40:674-681 (1997)

37) US 4801540

38) US Patent Application Serial No. 10/808,689

39) US Patent Application Serial No. 10/219,694

Documents 34 and 37 are being made of record in the instant application in this Information Disclosure Statement, supplied with Forms PTO-1449 and copies of the cited non U.S. patent documents. Documents 38 and 39 have already been made of record in the instant application in Information Disclosure Statements, supplied with Forms PTO-1449,

filed March 29, 2006. In accordance with the requirements of 37 C.F.R. §1.98, documents 28, 35 and 36 are listed below for consideration by the Examiner, and copies of the non U.S. patent documents are provided herewith.

The table below includes a column that provides a space next to each document to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document
	10	Hochepied <i>et al.</i> , "Breaking the Species Barrier: Derivation of Germline-Competent Embryonic Stem Cells from Mus spretus x C57BL/6 Hybrids" <i>Stem Cells</i> 22:441-447 (2004)
	11	Irvine <i>et al.</i> , "Engineering chromosomes for delivery of therapeutic genes", <i>Trends Biotechnol.</i> 23(12):575-583 (2005)
	12	Kuhholzer <i>et al.</i> , "Advances in Livestock Nuclear Transfer", <i>Proc. Soc. Exp. Biol. Med.</i> 224:240-245 (2000)
	13	Oback <i>et al.</i> , "Practical aspects of donor cell selection for nuclear cloning", <i>Cloning and Stem Cells</i> 4:169-174 (2002)
	14	Sang, "Prospects for transgenesis in the chick" <i>Mechanisms of Development</i> 121:1179-1186 (2004)
	15	Stice <i>et al.</i> , "Cloning: New breakthroughs leading to commercial opportunities", <i>Therigeneology</i> 49:129-138 (1998)
	16	Wolf <i>et al.</i> , "Nuclear transfer in mammals: Recent developments and future perspectives", <i>J. Biotech.</i> 65:99-110 (1998)
	17	Yanagimachi, "Cloning: Experience from the mouse and other animals", <i>Mol. Cell. Endocrin.</i> 187:241-248 (2002)
	26	Bryant <i>et al.</i> "Origins and complexes: the initiation of DNA replication", <i>J. Experimental Biology</i> 52(355):193-202 (2001)
	28	Hall <i>et al.</i> , "The rapidly evolving field of plant centromeres" <i>Curr. Opin. Plant Biol.</i> 7:108-114 (2004)
	35	Borisjuk, N.V. <i>et al.</i> , "Tobacco ribosomal DNA spacer element stimulates amplification and expression of heterologous genes" <i>Nature Biotech.</i> , 18:1303-1306 (2000)
	36	Donald <i>et al.</i> , "Ribosomal RNA genes specific to the B chromosomes in <i>Brachycome dichromosomatica</i> are not transcribed in leaf tissue" <i>Genome</i> 40:674-681 (1997)

Applicant also makes known to the Examiner the following U.S. applications that are commonly owned and/or have one or more inventors in common:

Applicant : Gyula Hadlaczký et al.
Serial No. : 09/724,726
Filed : November 28, 2000

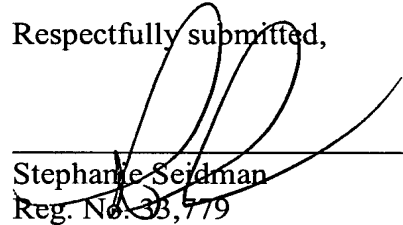
Attorney's Docket No.: 17084-004006/402E
Supplemental Information Disclosure Statement

<u>U.S.S.N.</u>	<u>Filing Date</u>	<u>Docket No.</u>
11/417,983	05/03/06	17084-018006/416F
11/480,175	06/29/06	17084-021002/420D
11/592,435	11/02/06	17084-004020/402S

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents or information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

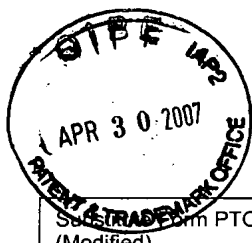
Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,



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Attorney Docket No. 17084-004006/402E
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Sheet 1 of 1

Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17084-004006/402E	Application No. 09/724,726
		Applicant Gyula Hadlaczky et al.	
		Filing Date November 28, 2000	Group Art Unit 1638

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	4,801,540	01/31/1989	Hiatt <i>et al.</i>	435	411	01/02/1987
	AB	2006/0095984	05/04/2006	Hadlaczky <i>et al.</i>	800	278	11/21/2005
	AC	2006/0143732	07/29/2006	Perez <i>et al.</i>	800	278	12/28/2005
	AD	2006/0150271	07/06/2006	Hadlaczky <i>et al.</i>	800	278	02/14/2006
	AE	2007/0061920	03/15/2007	Hadlaczky <i>et al.</i>	800	279	11/02/2006

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AF	0338266	10/25/1989	EP				

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AG	Assaad et al., "Somatic and Germinal Recombination of a Direct Repeat in Arabidopsis", <i>Genetics</i> 132:553-566 (1992)
	AH	Brown et al. "Dissecting the centromere of the human Y chromosome with cloned telomeric DNA" <i>Human Molecular Genetics</i> 3(8):1227-1237 (1994).
	AI	Brown et al., "Mammalian artificial chromosomes" <i>Curr. Opin. Genet. Dev.</i> 6(3):281-288 (1996)
	AJ	Campbell et al., "Totipotency or multipotentiality of cultured cells: applications and progress" <i>Theriogenology</i> 47:63-72 (1997)
	AK	Houdebine, "Production of pharmaceutical proteins from transgenic animals" <i>J. Biotech.</i> 34:269-287 (1994)
	AL	Kappell et al., "Regulating gene expression in transgenic animals" <i>Curr. Opin. Biotech.</i> 3:548-553 (1992)
	AM	McGovern, "The barriers to interspecific hybridization in domestic and laboratory mammals. II. Hybrid sterility" <i>Br. Vet. J.</i> 132:68-75 (1976)
	AN	Montoliu et al., "Germ Line Transmission of Yeast Artificial Chromosomes in Transgenic Mice" <i>Reprod. Fertil. Dev.</i> 6:577-584 (1994)
	AO	Mullins et al., "Perspective Series: Molecular Medicine in Genetically Engineered Animals", <i>J. Clin. Invest.</i> 97(7):1557-1560 (1996)
	AP	Mullins et al., "Transgenesis in nonmurine species" <i>Hypertension</i> 22(4):630-633 (1993)
	AQ	Nakahori et al., "A human Y-chromosome specific repeated DNA family (DYZ1) consists of a tandem array of pentanucleotides", <i>Nuc. Acids Res.</i> 14(19):7569-7580 (1986)
	AR	Schedl et al., "Transgenic mice generated by pronuclear injection of a yeast artificial chromosome", <i>Nucl. Acids Res.</i> 20(12):3073-3077 (1992)

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Disclosure Form (PTO-1449)